

## REMARKS/ARGUMENT

In the present Listing of the Claims, claim 57 is amended to recite:

57. The method of the controlled transdermal delivery of an agent encapsulated in microcapsules in a transdermal patch as a result of a controlled activation of the microcapsules in the transdermal patch using an ultrasound source or a heat source.

Claim 62 is amended for consistency with claim 61 from which it depends, and for typographic and numerical formality. No new matter is added by these amendments.

## PREVIOUS RESTRICTION REQUIREMENT

In the first action on this application, issued October 5, 2007, (being paper no 20070927), the Examiner required restriction of the application to one of eleven groups of claims, described by the Examiner as follows:

Group I, claim(s) 1-14, drawn to a method for delivering a substance transdermally by providing a substance within microcapsules onto a patch on the skin, then applying energy to the patch to release the substance.

Group II, claim(s) 15-31, drawn to a patch comprising an inner and outer disc.

Group III, claim(s) 32-47, drawn to a composition comprising a substance within microcapsules that are ruptured by a change in chemical potential.

Group IV, claim(s) 48, drawn to a composition comprising agents encapsulated in microspheres and a pressure-sensitive adhesive.

Group V, claim(s) 49, drawn to a composition comprising agents encapsulated in microspheres and hydrogel.

Group VI, claim(s) 50, drawn to a composition comprising agents encapsulated in microspheres and a hydrocolloid.

Group VII, claim(s) 51, drawn to a composition comprising agents encapsulated in microspheres and a medium in a patch.

Group VIII, claim(s) 52, 53, and 57-62, drawn to a method for delivering an encapsulated agent by applying ultrasound.

Group IX, claim(s) 54 and 57-62, drawn to a method for delivering an encapsulated agent by applying heat.

Group X, claim(s) 55, drawn to a device comprising ultrasound sources.

Group XI, claim(s) 56, drawn to a device comprising heating sources.

Claims 57-62 are linking claims and, if Group VIII or IX is elected, will be examined to the extent they read on the elected Group.

In the response filed December 7, 2007, Applicant provisionally elected **Group I** (being claims 1-14). Applicant partially traversed the election requirement for Groups VIII (claims 52-54) and IX, (claims 57-62). Applicant withdrew without prejudice the non-elected claims of Groups VIII and IX.

In the present action mailed March 6, 2008, the Examiner, finding the Applicant's arguments against restriction as applied to Groups I, VIII, and IX persuasive, withdrew this aspect of the restriction requirement. Accordingly, in the present response, Applicant reclassifies the claims of GROUP VIII (52-54) and Group IX (57-62) from the status of "withdrawn" to "previously presented," thereby prosecuting in the instant application claims 1-14, 52-54, and 57-62. The previously non-elected claims of Groups II-VII, X, and XI namely claims 15-51, 55-56, are canceled, the Applicant reserving the right to prosecute these canceled claims in future continuing patent applications.

### **PREVIOUS ELECTION OF SPECIES**

In the action mailed October 5, 2007, (being paper no. 20070927), the Examiner also required election of a single species for examination. The species described by the Examiner were as follows:

Substances in Groups I-III: (a) drug, (b) biologically active compound, (c) excipient, (d) skin permeation enhancer, (e) insulin, and (f) vitamin, as in claims 9-12, 27-30, and 43-46.

Active agents in Groups VIII and IX: numerous, as in claims 58-62.

In the response filed December 5, 2007, Applicant provisionally elected **Species (b)** (biologically active compound) from Groups I-III, while nevertheless traversing the requirement for election of species, from Groups VIII and IX.

In the present action mailed March 6, 2008, Application acknowledges with appreciation that the Examiner, finding persuasive the Applicant's arguments against election of species for Groups I-III, withdrew the election requirement as applied to Groups I-III.

### ELECTION OF SPECIES

The Examiner maintains the election requirement among the active agents recited in the method claims 58-62.

In response thereto, should the Examiner not find the generic claim allowable, Applicant hereby elects with traverse the method employing **insulin** as the encapsulated agent. Claims 57, 58 and 61 (reciting "hormone") read on the elected species. Applicant reserves the right to prosecute claims reciting the unelected agents mentioned in claims 59-62 in future continuing applications.

The Examiner is invited to revisit the election requirement in view of the amendment to claim 57, which is intended to clarify that the method recited applies to an agent in a transdermal patch that is encapsulated in microcapsules. Applicant is **not** seeking to claim the compounds and compositions that are described within the specification and recited as agents in the claims. An important aspect of the invention is the ability to deliver the active substance through at least one layer of the skin. The compounds are examples of encapsulated agents useful in performance of the claimed **methods**. No one specific substance or agent of the Examiner's list of "species" is critical for the operation of the invention. The term "encapsulated agent" is intended to mean any substance for which transdermal or subdermal delivery is to be accomplished, as described or example in ¶ 0023 of specification.

## **CONCLUSION**

This is intended to be a complete response to the outstanding Examiner's Action mailed March 6, 2008. Any questions or comments should be directed to the undersigned attorney of record.

Respectfully submitted:

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